

**Remarks:**

Applicant has carefully studied the non-final Examiner's Action mailed November 21, 2003 and all references cited therein. The explanatory remarks contained herein are believed to be fully responsive to the Action. Accordingly, this important patent application is believed to be in condition for allowance.

***Election/Restrictions***

Applicant confirms the provisional election to prosecute the claims of species A, claims 1-23. Claims 24-32 have therefore been cancelled without prejudice to their presentation in a future patent application.

***Oath/Declaration***

The oath or declaration stands objected to as defective because it does not recite that the named inventors are the original and first inventors. A new Declaration in compliance with 37 CFR 1.67(a) is attached hereto to overcome this ground of rejection.

***Drawings***

The drawings stand objected to because the vacuum source, sinusoidal configured opening, sawtooth configured opening, flow tube mounted on an exterior surface and flow tube formed within the lumen are claimed but not illustrated. The vacuum source will not be sold as a part of the invention, so claim 1 is amended to recite that the structure is adapted for connection to a vacuum source, thereby removing the vacuum source from the positively claimed limitations of claim 1, currently amended, and thereby removing any need to illustrate such vacuum source. Moreover, independent claim 1 includes no limitations to any specific configuration of the opening formed in the inner tube so the limitations in the dependent claims to a corkscrew (claim 5), sinusoidal (claim 6) or sawtooth (claim 7) opening are not required. Accordingly, rather than submit new drawings, those claims are cancelled. The same observation applies to the limitations in dependent claims Nos. 11-13 and 19-21 concerning the precise location of the flow tube. Dependent claims 5-7, 11-13, and 19-21 are cancelled without prejudice to their presentation in a future patent application and without disclaimer to their respective subjects matter.

### *Specification*

The specification stands objected to because each claim must be the object of a sentence. The Office's software inserts the term "Claims" in the last line of the specification. Accordingly, the term "Claims" has been changed to: "We claim:"

### *Claim Objections*

Claims 1-23 stand objected to because of the following informalities: The claim numbers include brackets. The Office requires deletion of such brackets and Applicant has performed the required deletion for all of said claims 1-23. However, this ground of rejection is rendered moot as it relates to claims 5-7, 11-14, and 19-23 in view of the cancellation of said claims. Applicant respectfully points out that the application was electronically filed and the inclusion of the character "c" as well as the bracketing of the claim numbers is a function of the software provided by the PTO.

Claim 10 is amended to depend from claim 9 to provide antecedent basis for "said irrigating means." Claim 15 (not claim 14) has been amended to depend from claim 8 to provide antecedent basis for "said motor means." The rejection relating to the limitation "removable" in line 1, claim 23 has been rendered moot by the cancellation of said claim 23. The subject matter of said claim has been added to independent claim 16 and the limitation is properly spelled as "removably" in said claim 16, currently amended.

### *Claim Rejections - 35 U.S.C. § 103*

Applicant acknowledges the quotation of 35 U.S.C. § 103(a).

Applicant further acknowledges the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made. With the cancellation of claims 24-32, the remaining claims (1-4, 8-10, and 15-18) are still commonly owned by the joint inventors.

Claims 1, 7, 8 and 15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Shuler in view of Alberico. Cancellation of claim 8 has rendered moot this ground of rejection as it relates to said claim 8. Reconsideration and withdrawal of this ground of rejection as it relates to claims 1, 7, and 15 is requested for the following reasons.

The Office acknowledges that Shuler lacks a hollow needle having a pointed end. The Office contends that Alberico includes a needle having a pointed end and that it would have been

obvious to one of ordinary skill in the art at the time Applicant's invention as claimed was made to combine the teachings of Shuler and Alberico to arrive at the claimed invention.

It is significant to note, however, that if an attempt is made to combine the respective teachings and suggestions of Shuler and Alberico in an effort to re-create the claimed invention, several difficulties appear. For example, the pointed end of Alberico outer tube 12 is really just half a point. As described by Alberico: "The outer tube 12 is defined by a smooth sidewall 16 and an end 18 defined by a slanted end wall 19 with a point 20." [0017, lines 4-6]. Inner tube 14 has a point 24 that fits within the interior of point 20 [0017, lines 6-8]. An opening 26 is formed in the end of the outer tube and an opening 28 is formed in the end of the inner tube. [0017, lines 8-9]. Accordingly, Alberico includes no complete point as does Applicant.

More importantly, Alberico's structure has no utility if opening 26 is closed to transform the Alberico structure into an outer tube 12 having a pointed end as in Applicant's claimed invention. If providing Alberico's outer tube 12 with a pointed end would render Alberico inoperable, it cannot be said in fairness to Applicants that it would have been obvious to so modify Alberico.

By the same logic, transforming opening 88 of Shuler into a closed, pointed end as claimed by Applicant would render useless teeth 102. Therefore it cannot be said in fairness to Applicants that it would have been obvious to so modify Shuler under the influence of Alberico to suggest or anticipate Applicant's invention as now claimed.

It is also important to observe that inner tube 16 of Alberico has a half-pointed distal end as aforesaid and thus Alberico teaches away from an inner tube having a flat distal end as claimed by Applicant.

Inner tubular member 16 of Shuler has teeth 102 formed therein and such structure also teaches away from Applicant's flat-end inner tube.

Thus, no combination of Shuler and Alberico suggests the flat distal end of Applicant's inner tube. The flat structure of the distal free end of Applicant's inner tube 50 is clearly depicted in the drawings so the amendment to paragraph [0050] of the specification pointing out such flat distal end does not constitute new matter. Moreover, the advantage gained by such flat distal end is inherent in the invention so it is not new matter to point out the advantage realized by said flat distal end.

No combination of Shuler and Alberico would have suggested a hollow needle having a pointed distal end and an opening formed in a sidewall of the hollow needle in spaced relation to said pointed distal end, together with an inner tube having a flat distal end rotatably mounted therein. It follows that no combination of Shuler and Alberico would have suggested an inner tube having a flat distal end and an opening formed in a sidewall thereof that intermittently enters into registration with the opening formed in the hollow needle as the inner tube undergoes rotation where the distal end of the opening formed in the inner tube is very close to the pointed distal end of the hollow needle due to the flat distal end of the inner tube.

Claim 2 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Shuler in view of Alberico as applied to claim 1, and further in view of Klein et al. (hereinafter "Klein"). Reconsideration and withdrawal of this ground of rejection is requested because Klein discloses a cutting head having a helical aperture 148 formed therein but no vacuum source and no filter trap. Instead, Klein employs a balloon to push the cutting head against tissue to be cut. When the balloon is inflated, it pushes the cutting head into tissue and part of said tissue then enters into helical aperture 148. Accordingly, Applicant acknowledges that claim 2 is allowable because it depends from claim 1, currently amended.

Claims 3-6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Shuler in view of Alberico as applied to claim 1. Cancellation of claims 5 and 6 has rendered moot this ground of rejection as it relates to said claims 5 and 6. Applicant acknowledges that claims 3 and 4 are allowable because they depend from claim 1, currently amended.

Claims 9-14 and 16-23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Shuler in view of Alberico as applied to claim 1, and further in view of Turturro et al. (hereinafter "Turturro"). Cancellation of claims 11-14 and 19-23 has rendered moot this ground of rejection as it relates to said claims 11-14 and 19-23. Reconsideration and withdrawal of this ground of rejection as it relates to claim 9 (irrigating means) and claim 10 (irrigating means including a flow tube) is requested because said claims depend from claim 1, currently amended. Reconsideration and withdrawal of said ground of rejection as it relates to claims 16-18 is requested because independent claim 16, currently amended, includes the same limitations as claim 1, currently amended, as well as further limitations to the rotation means being a motor means, a hand-held housing for said motor means, together with the limitations of now-cancelled claims 22 and 23. Dependent claims 17 and 18 are respectively drawn to the irrigation means

generally and to the flow tube that provides the irrigation means and are allowable because they depend from said independent claim 16, currently amended.

It should further be noted that independent claims 1 and 16, as currently amended, both include the limitations of cancelled claim 14. Although Turturro includes a filter trap, such filter trap is in the context of a biopsy tool having no rotating parts. Applicant's invention is required to suggest merging the teachings of Turturro with the teachings of Shuler and Alberico.

Applicant acknowledges that functional "whereby" clauses do not positively recite structural limitations. Applicant has carefully amended said clauses to place most of them in structural form. Independent claims 1 and 16 are now believed to define over all references of record in any combination.


#### Conclusion

Applicant agrees that the art made of record and not relied upon is not more pertinent to the invention as now claimed than the art cited as a reference against the claims as filed.

Entry of a Notice of Allowance is solicited. If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (727) 507-8558 is requested.

Very respectfully,

SMITH & HOPEN

By: 

Dated: February 16, 2004

Ronald E. Smith  
Suite 220  
15950 Bay Vista Drive  
Clearwater, FL 33760  
(727) 507-8558  
Attorneys for Applicant

#### CERTIFICATE OF FACSIMILE TRANSMISSION

(37 C.F.R. 1.8(a))

I HEREBY CERTIFY that this Amendment A, including Introductory Comments, Amendments to the Specification, Amendments to the Claims, and Remarks, is being transmitted by facsimile to the United States Patent and Trademark Office, Art Unit 3736, Attn: Mr. David J. McCrosky, (703) 872-9302 on February 16, 2004.

Dated: February 16, 2004

  
Deborah Preza